



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA-2019-N-3065]

RIN 0910-AI39

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Delayed

Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: As required by an order issued by the U.S. District Court for the Eastern District of Texas, this action delays the effective date of the final rule (“Tobacco Products; Required Warnings for Cigarette Packages and Advertisements”), which published on March 18, 2020.

The new effective date is January 9, 2023.

DATES: The effective date of the rule amending 21 CFR part 1141 published at 85 FR 15638, March 18, 2020, and delayed at 85 FR 32293, May 29, 2020; 86 FR 3793, January 15, 2021; 86 FR 36509, July 12, 2021; and 86 FR 50854, September 13, 2021, is further delayed until January 9, 2023.

FOR FURTHER INFORMATION CONTACT: Courtney Smith, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1371, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of March 18, 2020, the Food and Drug Administration (FDA or Agency) issued a final rule establishing new cigarette health warnings for cigarette packages and advertisements. The final rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31)

that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning label statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act of 1965 (Pub. L. 89-92) to require each cigarette package and advertisement to bear one of the new required warnings. The final rule specifies the 11 new textual warning label statements and accompanying color graphics. Pursuant to section 201(b) of the Tobacco Control Act, the rule was published with an effective date of June 18, 2021, 15 months after the date of publication of the final rule.

On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.¹ On May 8, 2020, the court granted a joint motion to govern proceedings in that case and postpone the effective date of the final rule by 120 days.² On December 2, 2020, the court granted a new motion by the plaintiffs to postpone the effective date of the final rule by an additional 90 days.³ On March 2, 2021, the court granted another motion by the plaintiffs to postpone the effective date of the final rule by an additional 90 days.⁴ On May 21, 2021, the court granted another motion by the plaintiffs to postpone the effective date of the final rule by an additional 90 days.⁵ On August 18, 2021, the court issued an order to postpone the effective date of the final rule by an additional 90 days.⁶ On November 12, 2021, the court issued another order to postpone the effective date of the final rule by an additional 90 days.⁷ The court ordered that the new effective date of the final rule is January 9, 2023. Pursuant to the court order, any

¹ *R.J. Reynolds Tobacco Co. et al. v. United States Food and Drug Administration et al.*, No. 6:20-cv-00176 (E.D. Tex. filed April 3, 2020).

² *R.J. Reynolds Tobacco Co.*, No. 6:20-cv-00176 (E.D. Tex. May 8, 2020) (order granting joint motion and establishing schedule), Doc. No. 33.

³ *R.J. Reynolds Tobacco Co.*, No. 6:20-cv-00176 (E.D. Tex. December 2, 2020) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 80.

⁴ *R.J. Reynolds Tobacco Co.*, No. 6:20-cv-00176 (E.D. Tex. March 2, 2021) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 89.

⁵ *R.J. Reynolds Tobacco Co.*, No. 6:20-cv-00176 (E.D. Tex. May 21, 2021) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 91.

⁶ *R.J. Reynolds Tobacco Co.*, No. 6:20-cv-00176 (E.D. Tex. August 18, 2021) (order postponing effective date), Doc. No. 92.

⁷ *R.J. Reynolds Tobacco Co.*, No. 6:20-cv-00176 (E.D. Tex. November 12, 2021) (order postponing effective date), Doc. No. 93.

obligation to comply with a deadline tied to the effective date is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date.

To the extent that 5 U.S.C. 553 applies to this action, the Agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the *Federal Register*, is based on the good cause exception in 5 U.S.C. 553(b)(B). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The 90-day postponement of the effective date, until January 9, 2023, is required by court order in accordance with the court's authority to postpone a rule's effective date pending judicial review (5 U.S.C. 705). Seeking prior public comment on this postponement would have been impracticable, as well as contrary to the public interest in the orderly issuance and implementation of regulations.

Dated: December 3, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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